

MTF Formulary Management for Phosphodiesterase-5 (PDE-5) Inhibitors

Department of Defense Pharmacoeconomic Center

Uniform Formulary Decision: The Director of TMA has approved the recommendations from the May 2005 DoD P&T Committee meeting regarding formulary status of PDE-5 inhibitors on the Uniform Formulary (UF) and Extended Core Formulary (ECF). The ECF selection becomes effective 14 Jul 2005, and the non-formulary designations 12 Oct 2005.

Uniform Formulary (UF) Agents	Non-Formulary (NF) Agents
PDE 5 Inhibitors on ECF (NOT on BCF) MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
Vardenafil (Levitra)	Sildenafil (Viagra) Tadalafil (Cialis)

Key Points

- Use Levitra because it is clinically equivalent and at least 40% less expensive than other PDE-5 inhibitors for the treatment of erectile dysfunction (ED).
- As of Jan 2005, over 95% of MTF PDE-5 inhibitor prescriptions were for Viagra or Cialis. MTFs should review PDE-5 inhibitor utilization and switch as many new and refilled prescriptions as possible prior to **12 Oct 2005**.
- Medical necessity, prior authorization, and quantity limits apply to this drug class at all pharmacy points of service. See specific sections and summary table below.

Dosing Equivalents

Sildenafil Dose	Equivalent Vardenafil Dose*
Viagra 25 mg	Levitra 5 mg
Viagra 50 mg	Levitra 10 mg
Viagra 100 mg	Levitra 20 mg

Based on strengths and directions in Viagra and Levitra drug monographs

- The recommended starting dose for Levitra is 10 mg. A 5 mg starting dose is recommended for patients ≥ 65 years of age, or stable on alpha blocker therapy, or patients with moderate hepatic impairment.

Price Comparison

Phosphodiesterase-5 (PDE-5) Inhibitor Price Comparison at MTF	
Drug Strength	Price (July 2005) ^{abc}
Extended Core Formulary PDE-5 inhibitor	
Levitra 2.5, 5, 10, 20 mg	\$3.54/tab*
Non-formulary PDE-5 inhibitors	
Viagra 25 mg	\$5.82/tab
Viagra 50, 100 mg	\$5.72/tab
Cialis 5 mg	\$6.13/tab
Cialis 10 mg	\$6.07/tab
Cialis 20 mg	\$6.18/tab
Revatio 20 mg	\$6.68/tab

^a Actual price may vary slightly due to MTF-specific Prime Vendor discounts and/or fees

^b MTFs are prohibited from entering into any incentive pricing agreements in any form with PDE-5 inhibitor pharmaceutical manufacturers to receive additional discounts.

^c Prices based on bottle size of 30 tablets

* Flat pricing for all strengths

Prior Authorization

- ED: Males < 50 years of age require prior authorization (PA).

- PPH: All patients require a PA. Revatio (sildenafil) is now approved as a three times-daily 20 mg white tablet for pulmonary arterial hypertension (PAH), also known as primary pulmonary hypertension (PPH). Revatio should not be used for ED.
- PA requirements apply at MTFs, retail network pharmacies (TRRX), and the mail order (TMOP). Once established, a PA for PDE-5 inhibitors is good at any point of service for the patient's lifetime. For more information: www.tricare.osd.mil/pharmacy/prior_auth.cfm.

Quantity Limits (QL)

- Quantity limit applies collectively to all strengths of sildenafil, tadalafil, and vardenafil. No more than 6 tablets per 30 days (retail) or 18 per 90 days (TMOP) supply of any combination of these medications will be dispensed of PDE-5 inhibitors for treatment of ED. Quantity limits encompass all prescriptions filled at MTFs, TRRX, and TMOP. For more information: www.tricare.osd.mil/pharmacy/unif_form.cfm.

Medical Necessity (MN)

- MTFs must use the medical necessity criteria for Viagra or Cialis established by the DoD P&T Committee for patients who have failed an adequate trial of Levitra or who cannot be treated with Levitra. For medical necessity criteria see: website: <http://www.tricare.osd.mil/pharmacy/medical-nonformulary.cfm>. A Microsoft Word version of the TMOP/TRRX Medical Necessity form adaptable for MTF use is available on RxNET.
- Cialis or Viagra prescriptions filled in TRRX or TMOP do not validate that MN has been established. Non-active duty beneficiaries may receive NF medications at a higher co-pay to without establishing medical necessity. MTFs may check patient's MN status from all points of service by calling the DoD Pharmacy Operations Center (POC) at 1-866-275-4732. Select option # 2 for direct assistance.
- Once established, a MN has no expiration date.
- New or refill prescriptions dispensed after effective date will establish MN authorization in the patient's PDTS profile for TRRX and TMOP. MTFs must ensure the required MN criteria are met prior to dispensing prescriptions in order to maintain the integrity of the pharmacy benefit.

Criteria Requirements at a Glance

Established PDE-5 Patient					
Patient Status	Prescribed Medication	Condition	Requires PA	Requires MN	QL
Male 50 or older	Levitra	ED	No	No	QL for ED apply
Male 50 or older	Viagra or Cialis	ED	No	Yes	
Male < 50	Levitra	ED	No**	No	
Male < 50	Viagra or Cialis	ED	No**	Yes	
Any patient with PPH	Revatio*	PPH	No	No (does not apply)	Quantity to treat PPH

* Prior authorization criteria allow for the use of Revatio OR Viagra for patients with primary pulmonary hypertension, since patients may be stabilized on Viagra.

** For males under 50 y/o and PPH patients, it can be assumed that a PA has been approved for established patients.

PDE-5 Naïve Patient (PA not yet approved)					
Patient Status	Prescribed Medication	Condition	Requires PA	Requires MN	QL
Male 50 or older	Levitra	ED	No	No	QL for ED apply
Male 50 or older	Viagra or Cialis	ED	No	Yes	
Male < 50	Levitra	ED	Yes	No	
Male < 50	Viagra or Cialis	ED	Yes	Yes	
Any patient with PPH	Revatio*	PPH	Yes	No (does not apply)	Qty to treat PPH

* Prior authorization criteria allow for the use of Revatio OR Viagra for patients with primary pulmonary hypertension, since patients may be stabilized on Viagra.

References

- For the full clinical review of the PDE-5 Inhibitors and for discussion about UF decisions, log onto RxNET (the PEC's webforum) www.dodrxnet.org (under "File Library" forum, "DoD P&T Library" folder).
- Current/ future drug classes under review by the DoD P&T Committee: www.pec.ha.osd.mil/PT_Committee.htm
- TRICARE website for information on the Uniform Formulary: www.tricare.osd.mil/pharmacy
- TRICARE Formulary Search Tool: www.tricareformularysearch.org

POC: For more information email: donald.nichols@amedd.army.mil or dave.bennett3@amedd.army.mil

